TABLE 2.—FEDERAL FACILITIES SECTION

State	Site name	City/County	(Notes) [a]
* * * * *	*		*
OH	Mound Plant (USDOE)	Miamisburg	P
* * * * *	*		*

([a])
P=Sites with partial deletion(s).

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[FR Doc. 02–24641 Filed 10–1–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicaid & Medicare Services

42 CFR Part 482

[CMS–3018–N]

RIN 0938–AL15

Medicare and Medicaid Programs; Hospital Conditions of Participation: Clarification of the Regulatory Flexibility Analysis for Patients' Rights

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule; clarification of regulatory flexibility analysis.

SUMMARY: On July 2, 1999, we published an interim final rule with comment period introducing a new Patients' Rights Condition of Participation (CoP) that hospitals must meet to be approved for, or to continue participation in, the Medicare and Medicaid programs. Several aspects of that interim final rule with comment period were challenged, including its regulatory flexibility analysis (RFA). As a result of this action, a Federal court, without enjoining continued enforcement of the rule, ordered the Secretary of the Department Health and Human Services (DHHS) to complete a compliant RFA to accompany the interim final rule with comment period. This document addresses the court's order.

FOR FURTHER INFORMATION CONTACT: Jeannie Miller, RN, (410) 786–3164.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule that detailed our plans to revise all of the hospital conditions of participation (CoPs), emphasizing lessening Federal regulations to eliminate unnecessary structural and process requirements, focus on outcomes of care, allow greater flexibility to hospitals and practitioners to meet quality standards, and place a stronger emphasis on quality assessment and performance improvement. The proposed rule introduced our intent to include a new Patients' Rights CoP for hospitals. We solicited comments and received strong support for the establishment of the new CoP from the public, mental health advocacy groups, the media, and the Congress.

After the proposed rule was published, reports of injuries and deaths associated with the use of restraints and seclusion increased our concern about patient safety. State surveyors, patient advocacy groups, the media, and the public also brought complaints about hospital violations of patients' rights to our attention. These violations included denying or frustrating patients' access to care, denying patients' full involvement in their treatment, disregarding patients' advance directives, and denying patients access to their records. In the July 2, 1999 **Federal Register** (64 FR 36070), we published an interim final rule with comment period to address these concerns and assure patient safety. The rule set forth requirements supporting and protecting patients' rights in the hospital setting, specifically, the right to be free from the inappropriate use of seclusion and restraint, with requirements to protect the patient when use of either intervention is necessary.

B. Legal Challenge of the Interim Final With Comment Period

The interim final rule with comment period was challenged in United States District Court for the District of Columbia by the National Association of Psychiatric Health Systems, the American Hospital Association, the Sheppard and Enoch Pratt Foundation, Incorporated, and Acadia Hospital. (*See National Association of Psychiatric Health Sys.* v. *Shalala*, 120 F.Supp.2d 33 (D.D.C. 2000).) Plaintiffs challenged one provision of the new CoP, the requirement that hospitals must provide for an in-person evaluation of a patient by a physician or other licensed independent practitioner (LIP) within 1 hour of initiating the use of restraint or placing the patient in seclusion to address the patients' violent or aggressive behavior. (*See* § 482.13(f)(3)(ii)(C).)

On September 14, 2000, the Court ruled in favor of the Secretary with respect to the plaintiffs' challenge under the Administrative Procedures Act; however, the Court ruled against the Secretary with respect to the plaintiffs' claim that the rule failed to fulfill certain requirements of the Regulatory Flexibility Act (RFA). In its decision, the Court noted that the RFA requires—

- A succinct statement of the need for and objectives of the rule;
- A summary of and response to the significant issues raised by public comments to the RFA assessment in the notice of proposed rulemaking;
- A description and estimate of the number of small entities to which the rule will be applied;
- A description of the projected reporting and recordkeeping requirements of the rule, including an estimate of the effect that the recordkeeping requirements will have on small entities; and
- A description of the efforts the agency has taken to minimize the significant economic impact of the rule on small businesses, including a discussion of the less restrictive alternatives considered and rejected.

The Court, noting that the Secretary had not made a ''reasonable good faith effort to canvass major options and weigh their probable effects,'' concluded that the agency failed to satisfy the fifth element of the Regulatory Flexibility Act. The case was remanded to the Department of Health and Human Services for completion of a compliant RFA without enjoining continued enforcement of the requirements of the

interim final rule with comment period. Accordingly, we are publishing this notice to discuss the alternatives that we considered when developing the July 2, 1999 interim final rule with comment period.

II. Revised Regulatory Impact Analysis of the July 2, 1999 Rule

A. Introduction

When we published the July 2, 1999 interim final rule with comment period, we lacked critical factual reports, studies, and data that would have aided in the development of specific cost or savings estimates. This factor continues to be an obstacle in providing cost estimates on the impact of some of the requirements.

At the time of the publication of the July 2, 1999 interim final rule with comment period, at least 80 percent of the 6,116 inpatient hospitals that participate in the Medicare or Medicaid programs were subject to existing accreditation requirements pertaining to the use of restraints and seclusion. While the pre-1999 Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) requirements did not contain all elements addressed by the interim final rule with comment period, many parallel standards were in place. There were two major differences between JCAHO's standards and our standards. The first is that JCAHO did not require the 1-hour face-to-face assessment but instead required a phone call to the LIP. The second is that JCAHO's monitoring requirements were more stringent than ours. It is worth noting that JACHO is enforcing all of our requirements, including the 1-hour rule, when conducting accreditation surveys. Accredited hospitals operated in an atmosphere that emphasized the elimination of unnecessary restraint, monitoring use, and reporting sentinel events to the JCAHO. Therefore, we approximated that 4,893 facilities were already subject to restraint and seclusion requirements. The remaining 1,223 facilities (non-profit, proprietary, and government-funded) would be subject to any existing state laws concerning the use of restraint and seclusion. Additionally, at least two States (New York and Pennsylvania) had established detailed regulations and policies regarding the use of restraint and seclusion in State-run and private facilities. Therefore, we concluded that the majority of hospitals were already affected by restraint and seclusion-related requirements, even if they were not equal in all points to the requirements specified in the interim final rule with comment period. Thus, although Medicare- and Medicaid-participating hospitals have diverse characteristics, many are accredited; and therefore, could be assumed to have been meeting pre-existing accreditation standards at the time the interim final rule with comment period was published.

Furthermore, with the increasing amount of research and literature identifying the potential hazards associated with restraint use, some hospitals were already engaged in efforts to reduce the use of restraints. The variations among hospitals, the lack of data on the prevalence of restraint or seclusion use in hospitals, and the trend of restraint use reduction efforts created problems in the formulation of a specific estimate for the interim final rule with comment period. While these were obstacles to the formulation of an estimate for the interim final rule with comment period, we invite hospital feedback on these points so that we may use this information in formulation of the final rule and its impact estimate.

B. Anticipated Effects and Options Considered

1. Effects on Hospitals

a. Restraint and Seclusion (§ 482.13(e) and (f))

Our regulations in § 482.13(e) and (f) prohibit the use of restraint and seclusion for purposes of coercion, discipline, convenience or retaliation by staff. These regulations also establish procedures that apply when hospitals use restraint or seclusion.

We considered developing one set of general requirements regulating restraint and seclusion use in all hospitals. However, based on public comments and recent concern regarding the risks associated with restraint and seclusion use for behavior management situations, we concluded that one set of requirements did not afford patients with adequate protections. Moreover, we believe that it is important to maintain consistency between Federal and accreditation standards. Therefore, we adopted an approach to restraints and seclusion similar to the existing standards that JCAHO created (for example, differentiating between situations when a restraint is being used to manage behavior and the concept of time limited orders). Accordingly, we made a distinction between restraint use in the provision of acute medical and postsurgical care (§ 482.13(e)) and restraint and seclusion use for the management of aggressive or violent behavior (§ 482.13(f)).

b. Training (§§ 482.13(e)(5) and (f)(6))

Section 482.13(e)(5) requires that staff with direct patient contact (that is, staff who may be involved either with the application of a restraint or the monitoring, assessment, or reevaluation of a restrained or secluded patient's condition) are provided with ongoing education and training in the proper and safe use of restraints. Section 482.13(f)(6) parallels these requirements and adds that staff involved in the application of a physical restraint or seclusion to manage aggressive or violent behavior must receive additional training in alternative methods for handling behavior, symptoms, and situations that have been traditionally treated using restraints or seclusion.

When writing the interim final rule with comment period, we considered the burden of requiring training on the use of restraints and seclusion for all staff members with direct patient contact. We believed that some persons inaccurately construed the requirement to entail the training of dietary, administrative, housekeeping, and other types of staff who are not involved in the application or use of restraints or seclusion. (*See* Tag A797, Appendix A of the State Operations Manual, HCFA Pub. No. 7, page A196.)

Most hospitals that participate in Medicare or Medicaid already have some type of training program; therefore, we believed that these requirements refine existing programs rather than mandate new ones. JCAHO's standards are applicable to accredited hospitals (currently 80 percent of Medicare- and Medicaid-participating hospitals) and require a similar training program for staff involved with the application of restraints or seclusion. (See JCAHO's 2000 Comprehensive Accreditation Manual for Hospitals standard TX 7.1.1.3 (which indicates that staff orientation and education create a culture emphasizing prevention and appropriate use of restraint or seclusion as well as encouraging alternatives) and standard TX 7.1.3.1.4 (which requires that restraint or seclusion is only used correctly by competent, trained staff)).

Lastly, we considered no training requirements; however, the *Hartford Courant* newspaper series indicated that training programs are a key ingredient in assuring a reduction in patient injuries and deaths associated with the use of restraints and seclusion. To omit this requirement in the interim final rule with comment period would have been to leave a critical gap in the strategy to improve patient care and assure patient safety.

c. Face-to-Face Monitoring (§ 482.13(f)(4))

The hospital CoPs require continuous face-to-face monitoring of a patient who is simultaneously physically restrained and secluded to address violent or aggressive behavior. As an alternative, continuous monitoring may occur through the use of both video and audio equipment, with the monitoring occurring in close proximity to the patient to allow quick intervention when needed.

We agree that this requirement may incur costs for hospitals, depending on their current practice. However, we believed that the training required by the July 2, 1999 interim final rule with comment period equipped staff with alternative methods for handling violent or aggressive patient behavior thereby reducing overall use of restraint or seclusion.

We did not require that this monitoring be done by a registered nurse. It could be performed by a nursing assistant or other staff member who has completed the required training.

We considered only requiring periodic monitoring when the two interventions are used simultaneously. However, we concluded that the instances meriting dual use of restraint or seclusion would be so rare and extreme that they would indicate a need for greater staff vigilance. Restraint and seclusion can actually increase the patient's agitation, and staff should be available to help the patient regain self control, thus ending one intervention or both as quickly as possible. Leaving a distressed patient alone for half an hour or longer, not understanding what is happening to him or her, does not facilitate the patient's recovery of his or her self-control. We concluded that uninterrupted monitoring assures that if the patient becomes more distressed by the intervention, staff can assist quickly.

d. One-Hour Evaluation (§ 482.13(f)(3)(ii)(C))

The interim final rule with comment period requires face-to-face assessment, by a physician or other LIP within one hour of the initiation of the intervention, of a patient who has been restrained or secluded to manage his or her violent or aggressive behavior. We considered whether this requirement was impossible to fulfill because of the lack of available personnel, geographic barriers, and costs associated with this degree of coverage. We also considered whether a required onsite evaluation by a physician or LIP is too costly or without a demonstrable benefit in many cases.

When the interim final rule with comment period was published in July 1999, we were not aware of any data regarding the appropriateness of the 1-hour timeframe and we solicited, but did not receive, comments providing data undercutting this requirement.

In including the 1-hour provision, we considered that hospitals are required to have 24-hour physician coverage. Section 482.12(c)(3) requires that the governing body of the hospital must ensure that a doctor of medicine or osteopathy is on duty or on call at all times. The interim final with comment period did not change this requirement or require hiring of new staff or having a physician onsite at all times. When staff are trained in alternatives to restraint or seclusion, prevalence of use should decline so that restraint or seclusion is used only as a last resort. We understand that for certain patient populations, such as for those who have self mutilating behaviors, a requirement for recurring onsite visits to assess the use of a restraint that is part of the patient's treatment plan may not be needed or appropriate. We plan to address these uses in forthcoming interpretive guidelines. Additionally, we reiterate that uses of restraint that occur in conjunction with an acute care need do not trigger the need for evaluation of the patient by a physician or other LIP within one hour. These uses may include, for example, a patient who is attempting self-extubation or tearing at lines whose behavior cannot be handled through less restrictive means.

In establishing this requirement, we considered onsite physician-only assessment within half an hour, which is the policy in one State's mental health system. However, we believed that this timeframe would not be reasonable in rural or remote areas, and therefore; we did not impose this requirement.

We also considered less prescriptive approaches. For example, we could have drafted regulations that remained silent on this point. However, various sources of information, including the press indicated that the patient is at high risk for injury when being restrained or secluded in an effort to manage his or her violent or aggressive behavior. (*See* ''Deadly Restraint: A Hartford Courant Investigative Report,'' with articles from October 11 through 15, 1998). Often patients are medically complex, with concomitant medical and psychiatric symptoms and conditions. When staff must resort to restraint or seclusion to protect the patient or others, it is essential to examine: (1) The immediate situation, that is whether the patient has been injured by the intervention; (2) the patient's reaction to the intervention; (3) the patient's overall medical and psychiatric condition; and (4) whether the behavior may stem from a condition that can be remedied quickly. Such a determination is a medical decision that requires the integration of many pieces of information, and therefore; merits a physician's or other LIP's attention.

We also considered other options that may be perceived as less burdensome. We could have drafted regulations that remained silent on the timeframe for a physician's or other LIP's assessment of a restrained or secluded patient. This alternative may be feasible for the types or uses of restraint described in § 482.13(e). In these types of situations, we left to the physician's or other LIP's discretion the decision of whether immediate, inperson assessment is required. In an instance when an armboard is applied to prevent accidental dislodging of an intravenous needle, arguably the application of the restraint does not represent a significant change in the patient's status, nor does the armboard pose a grave hazard to the patient's health or safety. In contrast, a patient's attempt to self-extubate could warrant immediate physician attention, depending on the patient and whether this behavior represents a marked change in status. However, we believed that requiring an inperson assessment within 1 hour for the variety of restraint uses under § 482.13(e) was not feasible because of the wide range of circumstances covered by that standard.

On the other hand, § 482.13(f) is more focused. We considered whether immediate attention was necessary when restraint or seclusion was used to manage a patient's violent or aggressive behavior. We recognized that the types of behavior that warrant the patient's placement in seclusion or the application of restraint often create a situation in which both the patient and staff are at risk for injury. The patient who is resisting staff restraint in this situation is unlike the noncombative patient who had an armboard applied. This patient has transitioned from seemingly calm behavior into a state at which an extreme measure has been undertaken to protect him or her. As discussed in the preamble to the interim final rule with comment period, we concluded that quick, medical involvement is warranted to assure safety and to develop a plan to avert or diminish further conflict. We believed that the maximum timeframe of 1 hour

established by this rule is a reasonable one.

We also considered permitting a staff member to perform a patient assessment through telephone consultation with a physician or other LIP. Given the complexity of the patient population, we did not select this option. Physicians and LIPs are extensively trained in assessment of symptoms and behaviors, in physical examination and formulation of diagnoses and resulting treatment strategies. Staff who are onsite may have widely disparate assessment skills. Some hospitals may staff patient care areas with licensed practical nurses or other available staff. We are not persuaded that these staff members have the physical and psychiatric assessment skills that correspond to the medical complexity of a patient in crisis. Accordingly, we opted not to permit patient assessment through telephone consultation.

2. Effect on Beneficiaries

The implementation of the Patients' Rights CoP served to protect not only Medicare and Medicaid beneficiaries, but all patients receiving care in any of the 6,166 Medicare- and Medicaid-participating hospitals (that is, acute care, psychiatric, rehabilitation, long-term care, children's, and alcohol-drug) including small rural hospitals. Our goal is to safeguard against the mistreatment of all patients in these facilities including, but not limited to— (1) Deaths due to inappropriate restraint or seclusion use; (2) violation of patients' privacy and confidentiality in various aspects of the healthcare delivery process; and (3) systematic frustration of the patients' efforts to acquire his or her medical records. Patients benefit from the hospitals' focus on patients' rights. Through these protections, patient care can be delivered in an atmosphere of respect for an individual patient's comfort, dignity, and privacy. The interim final rule with comment period emphasizes the importance of staff training, adequate monitoring and assessment, and prompt evaluation of restrained or secluded patients. As these factors, lack of training, evaluation, monitoring, and assessment were involved in the deaths reported by the media, we believed that implementation of the Patients' Rights CoP would lead to a reduction in the number of restraint- and seclusion-related injuries and deaths in hospitals. The following chart represents the data that we have received from providers regarding deaths that may have been related to restraint or seclusion use:

Year	Number of Deaths
August 1999—December 1999[1]	14
2000	34
2001	22
January 2002–March 2002[2]	5
Total from August 1999–March 2002	75

[1] The interim final rule with comment period was published on July 2, 1999 and effective on August 2, 1999. Therefore, no data on deaths related to restraint or seclusion use was submitted by providers before August 1999.

[2] The latest data available is through March 2002.

3. Effects on the Medicare and Medicaid Programs

We did not expect the implementation of the new Patients' Rights CoP to generate significant costs to the Medicare or Medicaid programs. We did not believe that there would be any additional costs to the survey and certification program as compliance with this new CoP either would be reviewed through a routine, nonaccredited hospital survey, a validation survey or as part of a complaint survey.

C. Conclusion

The Patients' Rights CoP introduced new Federal requirements that in many instances reflected existing State, accreditation or professional standards. These new Federal requirements are set forth in six standards to ensure minimum protections of each patient's physical and emotional health and safety. These standards address the patients' right to—

- Be notified of his or her rights;
- Exercise his or her rights in regard to his or her care;
- Privacy and safety;
- Confidentiality of and access to his or her medical records;
- Freedom from restraints used in the provision of acute medical and postsurgical care unless clinically necessary; and
- Freedom from restraint and seclusion use to manage violent or aggressive behavior unless clinically necessary.

(Catalog of Federal Domestic Assistance Programs No. 93.773, Medicare—Hospital Insurance and No. 93.778, Medical Assistance Program)

Dated: September 24, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare and Medicaid Services.

Dated: September 26, 2002.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 02–24857 Filed 9–27–02; 9:51 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482, 483, and 484

[CMS–3160–FC]

RIN 0938–AM00

Medicare and Medicaid Programs; Conditions of Participation: Immunization Standards for Hospitals, Long-Term Care Facilities, and Home Health Agencies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: The provisions of this final rule will remove the Federal barrier related to the requirement for a physician to order influenza and pneumococcal immunizations in Medicare and Medicaid participating hospitals, long-term care facilities, and home health agencies. This final rule will affect vaccine-preventable diseases and will help improve adult vaccination coverage rates. It will facilitate the delivery of appropriate vaccinations in a timely manner, increase the levels of vaccination coverage, and decrease the morbidity and mortality rate of influenza and pneumococcal diseases.

DATES: *Effective date:* These regulations are effective on October 2, 2002.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 2, 2002.

ADDRESSES: In commenting, please refer to file code CMS–3160–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3160–FC, P.O. Box 8013, Baltimore, MD 21244–8013.